Rx Pharmacy TRICARE

## Prior Authorization Criteria for the PDE-5 Inhibitors

The phospohdiesterase-5 (PDE-5) inhibitors for erectile dysfunction include vardenafil (Levitra,Staxyn), sildenafil (Viagra), avanafil (Stendra) and tadalafil (Cialis). All of these agents (except Stendra) are used for a variety of conditions, including erectile dysfunction, pulmonary hypertension, Raynaud's phenomenon, benign prostatic hyperplasia, and post-prostatectomy. Two other agents, Revatio (sildenafil) and Adcirca (tadalafil) are marketed specifically for primary pulmonary hypertension. The DOD Pharmacy and Therapeutics Committee designated this class as subject to prior authorization.

Prior authorization for PDE-5 inhibitors is NOT required for male patients 40 years of age or older being treated for erectile dysfunction with Viagra. Prior authorization IS required for male patients less than 40 years of age being treated for erectile dysfunction, for ALL new erectile dysfunction patients being treated with Cialis, Staxyn, Levitra, or Stendra and for ALL patients being treated for primary pulmonary hypertension, Raynaud's phenomenon, benign prostatic hyperplasia, and post-prostatectomy uses.

**Coverage IS provided for:**

• PDE-5 inhibitors for male patients 18 to 39 years of age with an approved prior authorization for:

  • Organic erectile dysfunction (e.g., diabetes-related, vascular-related); or

  • Mixed organic/psychogenic erectile dysfunction; or

  • Drug-induced erectile dysfunction where the causative drug cannot be altered or discontinued.

• PDE-5 inhibitors for male patients with erectile dysfunction, 40 years of age and older.

  • Sildenafil (Viagra) – no prior authorization form required

  • Vardenafil ODT (Staxyn), vardenafil (Levitra),avanafil (Stendra) or tadalafil (Cialis) – step therapy PA applies (See criteria below).

• Sildenafil (Revatio or Viagra) or tadalafil (Cialis or Adcirca) for any patient with primary pulmonary hypertension. Sildenafil (Viagra) vardenafil (Levitra) or tadalafil (Cialis) for any patient with Raynaud's phenomenon or for preservation and/or restoration of erectile function post-prostatectomy. Note the usage for preservation/restoration of erectile function is limited to one year after surgery.

• Tadalafil 5 mg (Cialis 5mg) for patients with benign prostatic hyperplasia (BPH) meeting prior authorization criteria listed below.

**Prior Authorization Criteria for Cialis (tadalafil) 5mg for BPH**

All current and new users of Cialis (tadalafil) 5 mg daily (for BPH) must meet one of the following criteria in order for Prior Authorization to be approved:

1. Diagnosis of benign prostatic hyperplasia (BPH)
2. Dosage is 5 mg daily
3. Patient tried tamsulosin (Flomax) or alfuzosin (Uroxatral) and had an inadequate response.
4. Patient tried tamsulosin (Flomax) or alfuzosin (Uroxatral) and was unable to tolerate it due to adverse effects.
5. Treatment with tamsulosin (Flomax) or alfuzosin (Uroxatral) is contraindicated (for example due to hypersensitivity).

**Coverage IS NOT provided for:**

• Female sexual dysfunction, or

• Erectile dysfunction in males under 18 years of age, or

• Psychogenic erectile dysfunction

**Quantity Limits**

• Treatment of Erectile Dysfunction – The PDE-5 inhibitors are limited to a maximum of 18 tablets per 90 days from the MOP or 6 tablets per 30 days from retail network pharmacies. This quantity limit applies collectively to all three medications. This means that no more than 18 tablets per 90-day supply of any combination of these medications will be dispensed in the TRICARE Mail Order Pharmacy and no more than 6 tablets per 30-day supply of any combination of these medications will be dispensed by retail network pharmacies. (Note: Staxyn (vardenafil ODT) is available in packages of four (4) tablets each. The Mail Order Pharmacy cannot break packaging and must dispense this product in multiples of 4.)

• Treatment of Pulmonary Arterial Hypertension, Raynaud's phenomenon, post-prostatectomy preservation/restoration of erectile function, Benign Prostatic Hyperplasia (BPH) - Usual rules apply (90-day supply in the MOP or 30-day supply at retail network pharmacies, based on the directions for use on the prescription).

• Use of Multiple Pharmacy Points of Service – The amount of medication obtained by a patient from all Military Health System pharmacy points of service will be taken into account in the application of this quantity limit.

Medical necessity forms are available on the TRICARE Pharmacy website at http://tricare.mil/Pharmacy/Drugs.aspx

*Criteria approved through the Uniform Formulary decision-making process*

# Levitra and Staxyn (vardenafil) Prior Authorization Request Form



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To be completed and signed by the prescriber. To be used only for prescriptions which are to be filled through the Department of Defense (DoD) TRICARE pharmacy program (TPHARM). Express Scripts is the TPHARM contractor for DoD.

| | |
|---|---|
| MAIL ORDER and RETAIL | • The provider may **call**: **1-866-684-4488** or the completed form may be **faxed** to: **1-866-684-4477**<br>• The patient may attach the completed form to the prescription and **mail** it to: **Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954** or **email** the form only to: **TpharmPA@express-scripts.com** |

Prior authorization criteria and a copy of this form are available at **http://pec.ha.osd.mil/forms_criteria.php**. This prior authorization has no expiration date.

**Step 1** **Please complete patient and physician information** (please print):

Patient Name: _____ Physician Name: _____

Address: _____ Address: _____

_____ _____

Sponsor ID # _____ Phone #: _____

Date of Birth: Secure Fax #:

**Step 2** **Please consider the following:**

- Patients taking nitrates, either regularly or intermittently, should not receive PDE-5 inhibitors. Patients should be informed of the consequences should they initiate nitrate therapy while taking a PDE-5 inhibitor.
- Please see product labeling precautions for concurrent use with alpha blockers.

**Step 3** **1. Please indicate the patient's gender.**

| | |
|---|---|
| Female | Please go to **Section 1** for **Female patients** on this page |
| Male | Please go to **Section 2** for **Male patients** on page 2 |

## Section 1 – Female patients

| | | |
|---|---|---|
| **1. Is the PDE-5 inhibitor being prescribed for the treatment of sexual dysfunction?** | Yes<br>**Coverage not approved** | No<br>Proceed to Question **2** |
| **2. Is the PDE-5 inhibitor being prescribed for a diagnosis of pulmonary arterial hypertension (PAH)?** | Yes<br>**SKIP** to Question **4** | No<br>Proceed to Question **3** |
| **3. Is the PDE-5 inhibitor being prescribed for a diagnosis of Raynaud's phenomenon?** | Yes<br>Proceed to Question **4** | No<br>**Coverage not approved** |
| **4. What is the dosing regimen?** | | |

**Please go to Step 4 on Page 2.**

# Levitra and Staxyn (vardenafil) Prior Authorization Request Form



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## Section 2 – Male patients

| | | |
|---|---|---|
| **1.** Is vardenafil being prescribed for a diagnosis of pulmonary arterial hypertension (PAH)? | **Yes**<br>**SKIP** to Question **9** | **No**<br>Proceed to Question **2** |
| **2.** Is vardenafil being prescribed for treatment of Raynaud's phenomenon? | **Yes**<br>**SKIP** to Question **9** | **No**<br>Proceed to Question **3** |
| **3.** Is vardenafil being prescribed for preservation/restoration of erectile function after prostatectomy? | **Yes**<br>**SKIP** to Question **9**[1] | **No**<br>Proceed to Question **4** |
| **4.** Is the patient 40 years of age or older? | **Yes**<br>**SKIP** to Question **6** | **No**<br>Proceed to Question **5** |
| **5.** Is vardenafil being prescribed for the treatment of erectile dysfunction (ED) of organic origin or mixed organic/psychogenic origin, or drug-induced ED where the causative drug cannot be altered or discontinued? | **Yes**<br>Proceed to Question **6** | **No**<br>**STOP**<br>**Coverage not approved** |
| **6.** Has the patient tried Viagra (sildenafil) and had an inadequate response? | **Yes**<br>**Sign and date below** | **No**<br>Proceed to Question **7** |
| **7.** Has the patient tried Viagra (sildenafil) but was unable to tolerate it due to adverse effects? | **Yes**<br>**Sign and date below** | **No**<br>Proceed to Question **8** |
| **8.** Is treatment with Viagra (sildenafil) contraindicated? | **Yes**<br>**Sign and date below** | **No**<br>**Coverage not approved** |
| **9.** What is the dosing regimen? | | |
| **Please sign and date below** | | |

[1] Authorizations for preservation/restoration after prostatectomy are valid for 1 year.

**Step 4** **I certify the above is correct and accurate to the best of my knowledge.** Please sign and date:

Prescriber signature _____ Date _____